UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,739	01/18/2001	Robert Lawton	00-1278	9509

20306 7590 01/31/2003

MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	18

DATE MAILED: 01/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/765,739	LAWTON ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-20,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *17* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 22, 2002 has been entered.

2. Applicant's amendment is acknowledged. Claims 21 and 23 have been amended. Claims 35-38 have been added.

3. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

4. In view of Applicant's amendment the rejection of claims 21-24 under 35 U.S.C. 102(b), pages 12-13, paragraph 5 of the previous Office action is withdrawn.

Rejections Maintained

5. The rejection of claims 21-24 and newly submitted claims 35-38 under 35 U.S.C. 112, first paragraph is maintained for the reasons set forth on pages 2-5, paragraph 4 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *This is a written description rejection.*

The specification broadly describes as a part of the invention polypeptides consisting of the polypeptides SEQ ID Nos: 1-7. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states " that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. Variants SEQ ID Nos: 1-7 correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOs:1-7, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO: 1-7 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant urges that claims 21 and 23 have been amended to recite that the variants of SEQ ID Nos: 1-7 are phenotypically silent amino acid substitution variants and new claims 35-38 have been added that recite that the variants of SEQ ID Nos:1-7 are conservative amino acid substitution variants. Applicant urges that one skilled in the art would recognize that the Applicants were in possession of an isolated polypeptide of SEQ ID Nos: 1-7, phenotypically silent amino acid substitution variants of SEQ ID Nos: 1-7 and conservative amino acid substitution variants of SEQ ID Nos: 1-7. Applicant urges that the specification teaches that variants are phenotypically silent amino acid substitutions and/or conservative amino acid substitutions and provides detail guidance on how to construct such variants. Applicant urges that the specification teaches that the polypeptides do not comprise 100% identity to a polypeptide sequence shown in SEQ ID Nos: 1-7 are considered variants and the polypeptides have at least 85% identity to the polypeptides sequence shown in SEQ ID Nos: 1-7. Applicant urges that the specification defines the meaning of "identity" and explains that sequences are aligned for identity calculations using a mathematical algorithm. Applicants urges that the specification teaches variants that are phenotypically silent amino acid substitutions or conservative amino acid substitutions, that have at least 85% identity to SEQ ID NO:2 and that specifically bind to an anti-*Ehrlichia* antibody. Applicant refers to Bowie et

al, to support that methods of constructing variants and that tolerance to substitutions in protein sequences are known in the art. Applicant urges that the claimed variant have adequate written description in the specification.

Applicant's arguments filed November 22, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show that the specification is enabled for the full scope of the claims and therefore does not meet the written description requirement as set forth in 35 U.S.C. 112, first paragraph. The specification broadly describes a genus of isolated polypeptides. Applicant has provided no structural description accompanying the variant language recited in the claims. While the use of sequence algorithm techniques are known in the art, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. Therefore, only SEQ ID Nos. 1-7 and not the full breadth of the claim (i.e. variants such as phenotypically silent amino acid substitutions and/or conservative amino acid substitution variants) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Comments regarding the Bowie et al reference cannot be addressed since the reference was not enclosed with the Applicant's amendment and response.

6. The rejection under 35 U.S.C. 112, first paragraph is maintained for 21-24 and newly presented claims 35-38 for the reasons set forth pages 5-7, paragraph 5 of the previous Office Action.

The rejection was on the grounds that the are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-7 are directed to isolated polypeptides selected from the groups consisting of SEQ ID NOs: 1-7 and variants thereof.

The specification is enabling only for the polypeptides of SEQ ID NOs: 1-7 as disclosed in the specification. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states " that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). The specification teaches that there are many tolerable and conservative amino acid substitutions which can be made that are not critical to protein function (pages 7-9). There is no guidance provided as to which amino acids can be added, deleted or substituted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity/utility requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide structure from mere sequence data of a single polypeptide and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modifications, e.g., multiple substitutions. The sequence of some polypeptides is highly conserved

and one skilled in the art would not expect tolerance to any amino acid modification in such polypeptides.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other antigens having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptides that are variants of SEQ ID NOs: 1-7 in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

Applicant urges that substituted amino acids are phenotypically silent amino acid substitutions or conservative amino acid substitutions and one skilled in the art given the specification could design a polypeptide that is a phenotypically silent amino acid substitution variant or a conservative amino acid substitution variant of SEQ ID Nos 1-7. Applicant urges that the specification teaches polypeptides that have at least 85% identity to the polypeptides sequence shown in SEQ ID No: 2 and specifically binds to an anti-*Ehrlichia* antibody. Applicant urges that one skilled in the art could easily design and make a polypeptide that falls within the given percentage sequence identity and screen it for specific binding to an anti-*Ehrlichia* antibody. Applicant urges that only routine experimentation is necessary to design and make a phenotypically silent amino acid substitution variant or a conservative amino acid substitution variant and the preparation of these variants are well known and understood in the art. Applicant urges

that given the specification, one skilled in the art could make and use the phenotypically silent amino acid substitution variant polypeptides or conservative amino acid variant polypeptides of the invention without undo experimentation.

Applicant's arguments filed November 22, 2002 have been fully considered but they are not persuasive. The claims as amended encompass isolated polypeptides that are phenotypically silent amino acid substitution variants or conservative amino acid substitution variants of SEQ ID Nos: 1-7, each specifically binding to an anti-*Ehrlichia* antibody. The specification does not provide enablement for the full scope of the claimed invention. Applicant has provided no structural description accompanying the variant language recited in the claims. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar anti-*Ehrlichia* antibody binding activity are limited in any polypeptide and the result of such modifications is unpredictable. One skilled in the art would not expect any tolerance to modifications, e.g., multiple substitutions. The sequence of some polypeptides is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such polypeptides. One skilled in the art would require guidance in order to make and use the claimed isolated polypeptides commensurate in scope with the claims.

7. The rejection of claims 21-24 and newly submitted claims 35-38 under 35 U.S.C. 102(a) is maintained for the reasons set forth on pages 8-10, paragraph 4 of the previous Office Action.

The rejection was on the grounds that Waner et al teach the use of a device (i.e. a clinic ELISA test kit). Waner et al teach that *Ehrlichia canis* IgG antibody titers of serum samples were determined by using a commercial ELISA test kit containing plastic combs sensitized with *E. canis* antigen. Waner et al teach that the sera to be tested was incubated with the comb (containing antigen dots). Waner et al teach that after washing away unbound antibodies the comb were allowed to react with goat anti-dog IgG alkaline phosphatase conjugate. Waner et al teach that bound antibodies were detected with a precipitating chromogen, 5-bromo-4chloro-3-indolyl phosphate and nitro-blue tetrazolium. The polypeptide sequence contained on the plastic comb (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. The instructions for performing various immunoassays (i.e. western blot, reversible flow chromatographic binding assay, enzyme linked immunosorbent assay or indirect immunofluorescense assay) are well known in the art. The device of Waner, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Waner et al do not teach or suggest the use of any kind of *E. chaffeenis* polypeptide in a device. Applicant urges that SEQ ID Nos:3-7 of the present invention are *E. chaffeensis* polypeptides and therefore cannot be anticipated by Waner et al. Applicant urges that Waner et al do not teach or suggest the use of distinct *E. canis* polypeptides as shown in SEQ ID Nos:1-7. Applicant urges that Waner et al teach an antigen purified from *E. canis* infected cells in disclosed assays and Waner et al do not teach, suggest or inherently disclose the specific individual polypeptides shown in SEQ ID Nos:1-7. Applicant urges that Waner et al also teach the use of

reagents comprising whole infected cells or whole *E. canis* proteins derived from infected cells. Applicant urges that there is no teaching in Waner et al directly or inherently that would direct one of skill in the art to the particular defined sequences of SEQ Nos:1-7 for any reason. Applicant urges that Waner et al do not teach or suggest that the SEQ ID Nos:1-7 are sequences that would be useful as individual peptides apart from the entire *E. canis* infected cells or proteins and Waner et al provides no recognition or suggestion that the distinct polypeptides shown in SEQ ID Nos:1-7 or any other polypeptide fragments would be of diagnostic use. Applicant urges that Example 1 demonstrates an assay that uses a synthetic peptide which was more sensitive and specific than assays that use native *E. canis* antigens, (i.e. partially purified *E. canis* antigens). Applicant urges that the Office relies on the statement that the article of manufacture "appears" to be the same as the claimed invention and asserts that the claimed polypeptides are inherent in the teaching of the prior art without providing any reasoning or evidence why the claimed about 18-20 amino acid polypeptides as shown in SEQ ID NOs: 1-7 would be present in Waner et al. Applicant urges that Waner et al do not teach each and every element of claims 21-24.

Applicant's arguments filed November 22, 2002 have been fully considered but they are not persuasive. The claims are drawn to a device containing one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID Nos:1-7 and phenotypically silent amino acid substitutions variants thereof. It is the Examiner's position that there is nothing on the record to show that the claimed device differs the device of the prior art. Waner et al teach an ELISA that uses *E. canis*

antigen derived from mouse J774. A1-infected cells (page 241). The Examiner disagrees with Applicant's assertion that the *E. canis* antigen of the prior art is not apart from the infected cells, since Waner et al teach antigen was derived from the mouse J774. A1-infected cells. Applicant appears to be arguing limitations that are not in the claims the assertion that Waner et al do not identify the polypeptide fragments for diagnostic use. There is no requirement or limitation in the claims that the device be used for diagnostic purposes. However, Waner et al teach that the ELISA of the prior art can be use to confirm or reject a diagnosis of canine monocytic ehrlichiosis (CME) (page 242). Waner et al further teach that the ELISA kit can be used efficaciously during all phases of CME and the ELISA could be used to and in the diagnosis of CME (page 243). The Applicant refers to Example 1 and asserts that the assays disclosed therein are more sensitive because synthetic peptides are used instead of native *E. canis* antigens. There is no requirement or limitation in the claims that states a degree of sensitivity that must be reached in detecting *Ehrlichia* infection. Since the claimed invention encompass variants of SEQ ID Nos:1-7, one skilled in the art could reasonably conclude that the *E. canis* polypeptide of the prior art is a variant of SEQ ID Nos:1-7 since, Applicant has provided no side-by-side comparison to show that the claimed polypeptide differs from the *E. canis* polypeptide of the prior art. It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia canis* or *Enrlichia chaffeenis* and that the polypeptides detect the presence of *Ehrlichia* antibodies not that the claimed

polypeptides are from *Ehrlichia canis* or *Ehrlichia chaffeenis*. Therefore, Waner et al anticipate the claimed invention.

8. The rejection of claims 21-24 under 35 U.S.C. 102(b) maintained for claims 21-24 newly submitted claims 35-38 for the reasons set forth in pages 10-12, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Cadman et al teach a device (i.e. a cross dot blot apparatus), nitrocellulose paper was coated with *E. canis* antigen. Cadman et al teach that 0.7 μg of protein in TBS was use per dot. Cadman et al teach that test sera was incubated with the antigen (dots on nitrocellulose paper). Cadman et al teach that the bound antibody was detected with peroxidase-labeled goat anti-dog IgG and 4-chloronaphthol. The polypeptide sequence contained on the nitrocellulose membrane (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. The instructions for performing various immunoassays (i.e. western blot, reversible flow chromatographic binding assay, enzyme linked immunosorbent assay or indirect immunofluorescense assay) are well known in the art. The device of Cadman, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Cadman et al do not teach or suggest the use of any kind of *E. chaffeenis* polypeptide in a device. Applicant urges that SEQ ID Nos:3-7 of the present invention are *E. chaffeensis* polypeptides and therefore cannot be anticipated by Cadman et al. Applicant urges that Cadman et al do not teach or suggest the use of distinct *E. canis* polypeptides as shown in SEQ ID Nos:1-2. Applicant urges that Cadman et al teach an antigen purified from *E. canis* infected cells in disclosed assays

and Cadman et al do not teach, suggest or inherently disclose the specific individual polypeptides shown in SEQ ID Nos:1-2. Applicant urges that Cadman et al do not identify the polypeptide fragments to be use of any particular diagnostic use. Applicant urges that there is no teaching in Cadman et al directly or inherently that would direct one of skill in the art to the particular defined sequences of SEQ Nos:1-2 for any reason. Applicant urges that Cadman et al do not teach or suggest the SEQ ID Nos:1-2 are sequences that would be useful as individual peptides apart from the entire *E. canis* infected cells or proteins and Cadman et al provides no recognition or suggestion that the distinct polypeptides shown in SEQ ID Nos:1-2 or any other polypeptide fragments would be of diagnostic use. Applicant urges that Cadman et al do not teach each and every element of claims 21-24.

Applicant's arguments filed November 22, 2002 have been fully considered but they are not persuasive. The claims are drawn to a device containing one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID Nos:1-7 and variants thereof. It is the Examiner's position that there is nothing on the record to show that the teaching of the prior art do not anticipate the claimed invention. Cadman et al teach nitrocellulose paper containing *E. canis* antigen, therefore the prior art teaches polypeptides that are apart from whole cells. Applicant appears to be arguing limitations that are not in the claims. There is no requirement or limitation in the claims that the device be used for diagnostic purposes. However, Cadman et al teach an indirect fluorescent assay (IFA) which is the recommended diagnostic test for *E. canis* infection, and has shown to be both sensitive and specific (page 362, 1st column).

The Examiner disagrees with Applicant's assertion that Cadman et al do not identify the polypeptide fragments for diagnostic use nor do Cadman et al teach or suggest that the polypeptides of SEQ ID Nos:1-2. The claimed invention encompass variants of SEQ ID NO: 2, therefore one skilled in the art could reasonably conclude that the *E. canis* polypeptide of the prior is a variant of SEQ ID NO:2, since Applicant has provided no side-by-side comparison to show: that the device of the prior art differs from the device of the claimed invention. It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia canis* or *Ehrlichia chaffeenis* and that the polypeptides detect the presence of *Ehrlichia* antibodies not that the claimed polypeptides are from *Ehrlichia canis* or *Ehrlichia chaffeenis*. Therefore, Cadman et al anticipate the claimed invention.

Status of Claims

9. No claims allowed.

Conclusion

10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
January 27, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600